Remarks

Claims 1-24, and 32-39 are presented for the Examiner's review and consideration.

§103 Rejection

Claims 1-24 and 32-39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ferrante et al. (5,569,259) ("Ferrante") in view of Felt et al. (6,652,587) ("Felt"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

As noted in the rejection, Ferrante does not teach a method wherein the side surfaces [are] bondable together within the body by the application of an energy source operative to produce heat within the polymeric material.

The rejection cites Felt for providing evidence of a modular implant having abutting mateable side surface together within the body by the application of an energy source to enhance conformance and improve long term performance. Applicant respectfully disagrees with respect to Felt curing the deficiencies of Ferrante, and further suggests the foregoing does not provide the elements stated to be missing in Ferrante.

Felt

The portions of Felt cited in the rejection do not suggest or teach the claimed invention. For example, Col. 7, lns. 20-21 states "[an embodiment of Felt] can be implanted within an initial about one to about five minutes of the onset of its formation, and once implanted can be further molded or formed for a further period...".

A moldable or formable implant does not teach or disclose a plurality of implant portions having a bone contacting surface and a mateable side surface, the side surfaces bondable together by the application of an energy source operative to produce heat, as is claimed. Applicant therefore respectfully submits that the cited portion is not applicable to the claimed invention.

The rejection further cites Col. 5, ln. 1, "[Felt] permits the on site preparation or previous manufacture of a unicompartmental inter-positional arthroplasty device from polymeric materials such as polyurethane”. It is not seen how this obviates the claimed invention, alone or in combination with Ferrante.

The rejection further cites Col. 9, lns. 12-54, stating in part “using materials having 'shape memory' that permits the components to be easily inserted into the joint space, in a manner that permits the component(s) to assume or recover an alternative shape upon the application of energy (e.g., heat slightly above body temperature).” Again, Applicant respectfully submits that having shape memory is not equivalent to the bonding on a side surface as is claimed. Heat is used throughout Felt only to make a material more bendable, in contrast to the claimed invention which uses heat to produce bonding on a side surface.

The previous citation adds, “to prepare the bone surface itself, to provide suitable interfaces (e.g., adhesive interfaces and/or protrusions that can be further secured to the joint site or by smoothing of the femoral condyle or tibial plateau as needed), to treat one or more surfaces in order to provide them with different or improved properties as compared to the inherent properties of the material providing the surface”. This portion of the citation in fact teaches away from the claimed invention. Specifically, Felt states *a suitable interface is necessary*, and gives as examples adhesives, protrusions, to provide the surfaces with **different properties than they inherently have**.

The rejection additionally cites Col. 14, lns. 10-14, “... or other suitable fit sufficient to prevent lateral displacement to the extent desired. The resultant formed prosthetic implant can be provided with various features as described herein, including desired molded portions adapted to provide better fit or performance.” Felt clearly and consistently describes snap fits and adhesives and the like, and does not suggest here, or elsewhere, using heat to bond side surfaces. In fact, in the line previous to the cited portion, it is stated “Optionally, and preferably, the generally planar portions are provided with corresponding matable portions, e.g., in the form of grooves and tabs to provide a sliding fit, or a depression and corresponding projection to provide either a press fit, snap 10 fit...”. Thus, taking the quote in its entirety, there is a clear suggestion of a mechanical interlocking, and not of heat bonding on a side surface.

The rejection further cites Col. 17, lns. 61-67 which state “In an alternative embodiment, the surface can be provided by any of a series of metals, including titanium, stainless steel, cobalt chrome millithium alloys and tantalum. Other surface materials can include various ceramics and biologic polymers. The implantable material for the resurfacing can be formed ex vivo and/or in vivo as an injectable material that sets up to the molded shape. The methods for changing state from liquid to solid state include cooling or heating."

This citation again demonstrates that Felt is directed to using heat to change the shape of a part, which is not related to the claimed invention.

Finally, the rejection cites Col. 18, lns. 1-7, "The reaction can be exothermic or endothermic. The set-up can be light activated or chemically catalyzed or it could be heat activated. Examples of such systems include flowable polymers of two or more components, light activated polymers, and polymers cured either by catalysts or by heat, including body heat, or any suitable combination thereof."

To provide context to the citation, it is again necessary to include the immediately preceding lines, which state "The implantable material for the resurfacing can be formed ex vivo and/or in vivo as an injectable material that sets up to the molded shape. The methods for changing state from liquid to solid state include cooling or heating, the passage of time, which allows for a change of state, or a chemical reaction between different reactants."

Thus, taking the citation in context, Felt is clearly referring to a changing of state in order to be moldable, and the "set up" refers to **a final molded shape**. This clearly refers to fitting a part to the body, as described in detail in Felt, and not to bonding different implanted parts.

Thus, Applicant respectfully submits that Felt cannot cure the deficiencies of Ferrante.

Independent claims 1, 13 and 21 each recite, *inter alia*, implant portions each having a bone contacting surface and an abutting mateable side surface including polymeric material, the side surfaces bondable together within the body by the application of an energy source operative to produce heat within said polymeric material to form a unitary implant.

Independent claim 22 recites, *inter alia*, a plurality of separate implant portions each having a bone contacting surface and an abutting mateable side surface including polymeric material, the side surfaces bondable together in the body to form a unitary implant.

Independent claim 32 recites, *inter alia,* forming a plurality of separate joint replacement portions, each having a bone contacting surface and an abutting mateable side surface, at least the abutting surface including polymeric material; and, providing said plurality of separate implant portions, to be passed separately into the body, wherein said abutting surface of at least two of said separate implant portions are abutted and bonded together in the body through the application of ultrasonic energy operative to produce heat within the polymeric material to form a unitary implant.

The rejection states that Felt teaches to “enhance conformance and improve long term performance”, but that is clearly not directed to the claimed elements of the invention, and further in light of the above, Felt fails to cure the deficiencies of Ferrante.

In addition to the above, Ferrante and Felt, among other deficiencies, further fail to suggest or teach:

passing an implant through an opening in skin that is substantially less wide than the formed unitary implant, as is claimed in claims 1, 13, 21 and 22; and,

bonding a medial side and a lateral side of an implant together, where bonding is on a side surface using heat, as is claimed in claim 13.

Accordingly, Applicant respectfully submits that claims 1, 13, 21, 22 and 32 are patentable over Ferrante in view of Felt. As claims 2-12 and 38 depend from claim 1; 14-20 from claim 13; 23-24 and 39 from claim 22; and 33-37 from claim 32, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Ferrante in view of Felt for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejection.

Previously Submitted Rule 131 Affidavit

In a Rule 131 Affidavit sent March 30, 2007, Applicant stated that invention occurred prior to June 12, 2001, and that conveyance of the invention to a registered representative occurred prior to June 12, 2001. While this is factually correct, through inadvertent or typographical error, the date June 12, 2001 should have been June 14, 2001, which is the earliest priority date of US Patent 6,482,209 to Engh et al. Applicant respectfully submits that, at least because the intended date is later, the error has no substantive effect, and thus represents harmless error.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested.

If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410
(Docket No. 780-A03-012A).

Respectfully submitted,

/ Gary S. Winer /

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